to certain communications from State and foreign government officials because the same policy reasons that support nondisclosure of deliberative and predecisional memoranda generated by Federal government agencies justify withholding, in many circumstances, the advice and recommendations generated for FDA by State and foreign government counterparts.

The agency's ability to make sound decisions about the development and implementation of public health and harmonization initiatives is enhanced by access to the advice and recommendations of experts in State and foreign governments who are engaged in similar efforts in their own jurisdictions. The agency views this kind of consultation as functionally equivalent to the "intra-" or "interagency" deliberation more commonly protected by exemption 5 of the FOIA. Indeed, it is frequently the case that advice from a State or foreign health official whose responsibilities parallel those of FDA officials concerning the feasibility of a particular technical or harmonization regulation will be as relevant as similar recommendations solicited from employees in other Federal government agencies.

In order to encourage the most candid and useful exchange of information in these circumstances, FDA believes it is essential to have discretion to protect from public disclosure the advice and recommendations it receives from State or foreign government officials. Again, the same policy considerations apply as would apply to intraagency deliberations: State and foreign government officials are at least as likely as Federal employees to be inhibited from giving frank advice when they know that opinion will be made public.

The principle that documents generated outside a government agency" may still qualify for protection from public disclosure under exemption 5 of the FOIA has been endorsed by many courts. In recognizing the practical necessity that requires agency decisionmaking to depend on advice and opinions from sources beyond agency or Federal personnel, courts have adopted a "functional" test for assessing the applicability of exemption 5 protection, and included a variety of "nonagencies" within the threshhold definition of exemption 5 memoranda. (See, e.g., Formaldehyde Institute v. HHS, 889 F.2d 1118, 1123-1124 (D.C. Cir. 1989) (exemption 5's interagency threshold requirement applied to opinions solicited from outside scientific journal reviewers); Ryan v. Department of Justice, 617 F.2d 781, 790 (D.C. Cir. 1980) (exemption 5 applied to recommendations from Senators to Attorney General); *Mobil Oil Corp.* v. *FTC*, 406 F. Supp. 305, 315 (S.D.N.Y. 1976) (exemption 5 rationale applies to advice from State as well as Federal agencies). FDA believes the examples it has described in this document demonstrate that it is appropriate and necessary for FDA to be able to treat the exchange of advice and recommendations from foreign and State government officials as a functional part of the agency's deliberative process.

In addition to protecting certain advice and recommendations from State and foreign government officials which FDA utilizes in its decisionmaking processes, FDA also believes it should be able to cooperate with State and foreign government officials who request FDA input for deliberations within their own agencies.

Those State and foreign government agencies with which FDA most frequently consults operate, as does FDA, within laws that constrain their ability to share nonpublic information. In many circumstances, these agencies require assurances that FDA will not disclose to the public in response to a FOIA request certain information provided to FDA by a State or foreign govenment official. FDA has always been able to give such assurances with respect to proprietary or law enforcement information provided by State or foreign governments; under FDA's public information regulations. such information is subject to the same protection as if the information had been directly gathered or received by FDA. (See § 20.88(c)(1) and 20.89(a)). Indeed, FDA's regulations have for 20 years permitted the agency to provide additional assurances with respect to investigatory records that the State or foreign government will provide only upon assurance that protection will continue for some longer period of time.

However, FDA has not been able to provide similar assurances of confidentiality with respect to nonpublic information provided to FDA by State or foreign governments that is of a deliberative nature, reflecting internal deliberations of that other government entity or predecisional drafts of records that are intended to implement public health initiatives on the part of counterpart State or foreign government agencies.

As discussed above, FDA believes that when such counterpart officials provide advice to FDA on issues and initiatives that FDA is deliberating, that advice is the functional equivalent of advice that

would be provided by experts within the agency or by other Federal agency employees. Accordingly, under the amendments proposed to §§ 20.88 and 20.89, FDA would protect as interagency memoranda under exemption 5 of the FOIA the records it exchanged with foreign and State government health officials as part of FDA's efforts to reach a decision about initiatives it was considering. However, FDA believes the public health and FDA's relationships with foreign and State counterparts require that the agency be able to provide similar consultations to counterpart officials when it is those State or foreign government officials who request advice, and who require the exchange to remain nonpublic in order to protect their own deliberative processes. In most cases, because the foreign or State counterpart is providing FDA with information that is confidential commercial or investigatory information, FDA's published regulations permit FDA to protect those records from public disclosure. There have been situations, however, where a foreign government agency wishes to share with FDA a document that will not qualify for protection under the FOIA for proprietary or investigatory records, and which may not qualify under the deliberative process privilege discussed above because the decision that is being made is entirely within the jurisdiction of the foreign government counterpart. FDA believes international comity and the potential benefit to public health that may result from such consultations require the agency to attempt to honor such requests for confidentiality whenever it is possible to do so.

In circumstances where advice or information is provided by foreign governments pursuant to international agreements that provide for the nondisclosure of such exchanges, FDA believes the record generated by the foreign government and provided to FDA is not necessarily an "agency record" subject to FOIA and that FDA, therefore, might honor requests for confidentiality without contravening public disclosure requirements. The Supreme Court has delineated two broad tests for determining whether a document is an agency record for purposes of FOIA. The document: (1) Must be created or obtained by an agency, and (2) must be under the control of the agency when a FOIA request for the record is made. See United States Department of Justice v. Tax Analysts, 492 U.S. 136 (1989). When a foreign government shares